K102090

SpineSmith Cynch Spinal System – Visualif Interbody Fusion Implant System

510(k) Summary of Safety and Effectiveness

SUBMITTED BY	SpineSmith Partners, LP 93 Red River Austin, TX 78701
ESTABLISHMENT REGISTRATION NUMBER	3006404071 SEP 30 2010
CONTACT PERSON	**Laura LeBoeuf** Vice President – Quality and Regulatory Affairs Phone: 512-637-2068 Fax: 512-302-4920 Email: lleboeuf@spinesmithusa.com
SUBMISSION PREPARED BY	Lisa Peterson Kaedon Consulting, LLC Phone: 512-507-0746
DATE PREPARED	July 10, 2010
CLASSIFICATION NAME	Intervertebral Fusion Device with Bone Graft, Lumbar (Product Code: MAX)
DEVICE CLASS	Class II
REGULATION NUMBER	888.3080
COMMON NAME	Intervertebral Body Fusion Device
PROPRIETARY NAME	SpineSmith Cynch Spinal System – Visualif Interbody Fusion Implant System

IDENTIFICATION OF PREDICATE DEVICES:
The SpineSmith Visualif System was determined to be substantially equivalent to the previously cleared Cynch System (K090376, SpineSmith; Cleared 4/1/2009).

DEVICE DESCRIPTION:
The Visualif System is part of the Cynch Spinal System and is available in various sizes to accommodate individual patient anatomy. The Visualif implant is a lumbar intervertebral body fusion device that is intended to be implanted singularly via an open anterior approach. Visualif is a stand-alone device intended to be used with two (2) bone screws provided and the accompanying anterior cover plate assembly. NOTE: The cover plate assembly and screws are part of the implant construct.

Addition of an ALIF version to the existing Cynch System is intended to provide surgeons with additional surgical approach options. There are no changes with respect to indications or intended use as compared to the Cynch Spinal System cleared previously via K090376.

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INDICATIONS:
The Cynch System is indicated for intervertebral body fusion of the lumbar spine, from L2 to SI, in skeletally mature patients who have had six months of non-operative treatment.

The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion.

The Cynch System Visualif is a stand-alone device intended to be used with the two bone screws provided and the accompanying anterior cover plate. Should the physician choose to use fewer than the two screws provided, additional supplemental fixation cleared by the FDA for use in the lumbar spine must be used. The anterior cover plate must be utilized whenever the device is implanted using the bone screws provided.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS:
The purpose of this submission is to add the Visualif device, which may be implanted via an open anterior approach. The Cynch System implants are manufactured from PEEK Optima LT1 and contain three (3) radiopaque tantalum markers to assist the surgeon with proper placement of the device. The subject device (Visualif – ALIF device) has similar technological characteristics as the predicate devices identified above (SpineSmith's Cynch System per K090376). Specifically, the following characteristics support this conclusion:

- Intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis.
- 'U' shaped implant design to allow for placement of autograft bone
- Implant material: PEEK Optima LT1 per ASTM F2026 with radiopaque tantalum marker bar per ASTM F-560-05, and Titanium alloy screws/cover plate assembly per ASTM F-136
- Substantially equivalent results of non-clinical testing relative to static and dynamic testing (per ASTM F2077-03), subsidence (per ASTM F2267-04), and expulsion (per ASTM Draft Standard F-04.25.02.02)

DISCUSSION OF NON-CLINICAL TESTING:
The following non-clinical tests were conducted:

- Static and dynamic compression testing, conducted in accordance with ASTM F2077-03
- Static and dynamic compression-shear testing, conducted in accordance with ASTM F2077-03
- Subsidence testing, conducted in accordance with ASTM F2267-04
- Expulsion testing, conducted in accordance with ASTM Draft Standard F-04.25.02.02
- Wear Debris Characterization, conducted in accordance to ASTM F1877.

CONCLUSIONS:
The subject and predicate device share the same intended use, primary implant design and material of manufacture. The non-clinical mechanical test results demonstrate that any minor differences do not impact device performance as compared to the predicates and demonstrate that the Visualif System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Spine Smith Partners, LP
% Ms. Laura LeBoeuf
Vice President – Quality and Regulatory Affairs
93 Red River
Austin, Texas 78701

SEP 12 2011

Re: K102090
Trade/Device Name: Cynch Spinal System – Visualif Interbody Fusion Implant System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD
Dated: September 1, 2010
Received: September 3, 2010

Dear Ms. LeBoeuf:

This letter corrects our substantially equivalent letter of September 30, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other

requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K102090

SEP 30 2010

Device Name: **SpineSmith Cynch Spinal System - Visualif Interbody Fusion Implant System**

Indications for Use:

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The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion.

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Prescription Use ___X___ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K102090